

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

To: CARPMAELS & RANSFORD Attn. Tunstall, Christopher S 43-45 Bloomsbury Square London WC1A 2RA GRANDE BRETAGNE	26 FEB 2007 RECEIVED CARPMAELS & RANSFORD ACTIONED AA
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(PCT Rule 44.1)

Applicant's or agent's file reference P041832WO	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/IB2006/002792	International filing date (day/month/year) 03/08/2006
Applicant CILAG GMBH INTERNATIONAL	

1. The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Martine Eich
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NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P041832WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/IB2006/002792	International filing date (<i>day/month/year</i>) 03/08/2006	(Earliest) Priority Date (<i>day/month/year</i>) 30/08/2005
Applicant CILAG GMBH INTERNATIONAL		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- the international application in the language in which it was filed
 a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. **Certain claims were found unsearchable** (See Box No. II)

3. **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,

- the text is approved as submitted by the applicant
 the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- the text is approved as submitted by the applicant
 the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 1

- as suggested by the applicant
 as selected by this Authority, because the applicant failed to suggest a figure
 as selected by this Authority, because this figure better characterizes the invention
- b. none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2006/002792

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 1 169 935 A (S. E. D. A. T.) 7 January 1959 (1959-01-07)	1,5,6, 11,15-17
X		20-22
A	figures 1-4	2-4,7-10
A	the whole document	12-14, 18,19
A	----- WO 94/22511 A (IMMUNO AKTIENGESELLSCHAFT; BARTA, HELMUT; MOSER, FRANZ; SIMONICH, WALT) 13 October 1994 (1994-10-13) cited in the application the whole document	1-22
A	----- EP 0 240 787 A (PHARMA-GUMMI WIMMER WEST GMBH) 14 October 1987 (1987-10-14) cited in the application the whole document	1-22
	----- -/-	

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority, claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

14 February 2007

27/02/2007

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Reinbold, Sylvie

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2006/002792

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 5 137 516 A (RAND ET AL) 11 August 1992 (1992-08-11) figures 17-24 column 10, line 53 - column 13, line 11 -----</p>	1-22

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2006/002792

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
FR 1169935		A	07-01-1959	NONE		
WO 9422511	A	13-10-1994	AU CA DE DK EP ES HR JP US	6671394 A 2159204 A1 59407284 D1 691861 T3 0691861 A1 2126110 T3 940215 A2 8508182 T 5540666 A		24-10-1994 13-10-1994 17-12-1998 26-07-1999 17-01-1996 16-03-1999 31-08-1996 03-09-1996 30-07-1996
EP 0240787	A	14-10-1987	CA US	1270168 A1 4735311 A		12-06-1990 05-04-1988
US 5137516	A	11-08-1992	AR AT AU AU BE BR CA CH CZ DE DK ES FI FR GB GR HK HU IE IL IN IT JP JP LU NL NO NZ PL PT SE SE RU ZA	246185 A1 240790 A 639955 B2 6691290 A 1003835 A5 9006006 A 2030742 A1 687234 A5 9702029 A3 4037418 A1 281990 A 2038088 A6 905832 A 2654938 A1 2239180 A 90100824 A 19295 A 61207 A2 904240 A1 96487 A 179332 A1 1243541 B 3222962 A 3399524 B2 87851 A1 9002598 A 905125 A 236219 A 287996 A1 96005 A 469262 B 9003776 A 2108116 C1 9009514 A		29-07-1994 15-09-1995 12-08-1993 06-06-1991 23-06-1992 24-09-1991 29-05-1991 31-10-1996 11-08-1999 29-05-1991 29-05-1991 01-07-1993 29-05-1991 31-05-1991 26-06-1991 17-04-1992 17-02-1995 28-12-1992 05-06-1991 26-05-1995 27-09-1997 16-06-1994 01-10-1991 21-04-2003 25-08-1992 17-06-1991 29-05-1991 23-12-1992 12-08-1991 31-08-1992 14-06-1993 29-05-1991 10-04-1998 27-11-1991

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

		Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet)
Applicant's or agent's file reference see form PCT/ISA/220		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/IB2006/002792	International filing date (day/month/year) 03.08.2006	Priority date (day/month/year) 30.08.2005
International Patent Classification (IPC) or both national classification and IPC INV. A61M5/32		
Applicant CILAG GMBH INTERNATIONAL		

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx. 523656 eprmu d Fax: +49 89 2399 - 4465	Date of completion of this opinion see form PCT/ISA/210	Authorized Officer Reinbold, Sylvie Telephone No. +49 89 2399-7918
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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 the international application in the language in which it was filed
 a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material:
 on paper
 in electronic form
 - c. time of filing/furnishing:
 contained in the international application as filed.
 filed together with the international application in electronic form.
 furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2006/002792

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes:	Claims 2-4,7-10,12-14,18-19
	No:	Claims 1,5,6,11,15-17,20-22
Inventive step (IS)	Yes:	Claims
	No:	Claims 1-22
Industrial applicability (IA)	Yes:	Claims 1-22
	No:	Claims

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: FR-A-1 169 935
D2: WO 94/22511
D3: EP-A-0 240 787
D4: US-A-5 137 516

Novelty Article 33(2) PCT

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 1,5,6,11,15-17 and 20-22** does not seem to be new in the sense of Article 33(2) PCT.
 - 2.1. The document D1 discloses a needle assembly for a prefilled injection syringe comprising (Fig.1-5):
claims 1,5,6,11,15-17:
 - a needle holder (2) adapted to be secured to a syringe barrel of the injection syringe and a needle (11) secured to the needle holder
 - a needle sheath (capuchon 1), releasably connected at its distal end to the needle holder to form a sterile seal, and surrounding and shielding the needle
 - a needle seal (caoutchouc 10) located on the needle tip and arranged at least in part in the proximal end of the needle sheath
 - a closure element (chapeau 7) that closes off the proximal end of the needle seal
 - a closure connection between the closure element and the needle sheath configured as a non releasable and sterile barrier produced by means of bonding or welding (page 2 line 2)
 - 2.2. As the needle assembly of claim 1 is not new, the method of manufacturing a needle assembly disclosed in claims 20-22 are implicit disclosed in the document D1.

Inventive Step Article 33(3) PCT

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 2-4,7-10,12-14,18 and 19 does not seem to involve an inventive step** in the sense of Article 33(3) PCT.

In **claims 2-4,7-10,12-14,18 and 19 a slight change** (type of welding, sheath, material) in the device of D1 is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject matter of these claims also lacks an inventive step.

Re Item VII

Certain defects in the international application

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the document D1 is not mentioned in the description, nor are these documents identified therein.